

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 97,429)

In re Application of:)
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Robert D. Gilmore and)
Barbara J.B. Johnson.) Examiner: To be assigned
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Serial No.: 09 004,395) Art Unit: 1643
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Filed: January 8, 1998)
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For: RECOMBINANT P37/FLAA AS A)
DIAGNOSTIC TREATMENT)

TRANSMITTAL LETTER
VIA HAND DELIVERY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In regard to the above identified application:

1. We are transmitting herewith the attached:

- a. U.S. PTO Form 1449, Information Disclosure Statement (2 sheets) and attached references (46 references);
- b. Return postcard.

2. With respect to additional fees:

No fee is required.

3. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490.
A duplicate copy of this sheet is attached.

Respectfully submitted

McCormick, Backman, Hulbert & Berghoff
Reg. No. 35,285

PATENT
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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In order to comply with discretionary regulations 37 CFR 1.97 and 1.98, attached hereto is Form PTO-1449, and copies¹ of the documents listed thereon. These documents contain information which the Examiner may consider to be important in deciding whether to allow the present application to issue as a patent.

U.S. Patent Documents

Patent Number	Date	Name	Class	Subclass
4,888,276	Dec. 19, 1989	Shelburne	435	7
5,523,089	Jun. 4, 1996	Bergstrom et al.	424	262.1
5,554,371	Sep. 10, 1996	Caputa et al.	424	234.1
5,558,993	Sep. 24, 1996	Champion et al.	435	6
5,620,862	Apr. 15, 1997	Padula et al.		

I declare under penalty of perjury that the above is true and correct. If a foreign language document is cited, and an English language equivalent is known to the undersigned, the English language equivalent is also attached. If a foreign language patent document is cited, and an English language equivalent is known to the undersigned, the English language equivalent is also attached. If a foreign language document is cited, and no English language equivalent is known to the undersigned, the undersigned has not seen the original document. I declare under penalty of perjury that the undersigned is the inventor(s) of the subject matter described in the application, and that there is no conflict with the undersigned.

Other Documents

1. Anderson et al., "Prevalence of *Borrelia burgdorferi* in White-Footed Mice and *Ixodes dammini* at Fort McCoy, Wis.", Journal of Clinical Microbiology, Aug. 1987, pp. 1495-1497.
2. Barbour et al. "A *Borrelia*-Specific Monoclonal Antibody Binds of a Flagellar Epitope," Infection and Immunity, May 1980, p.p.549-554.
3. Barbour et al. "Antibodies of Patients With Lyme Disease to Components of the *Ixodes Dammini* Spirochete," Journal of Clinical Investigation, August 1983, Vol. 72, pp. 504-515.
4. Barbour et al. "Biology of *Borrelia* Species." Microbiological Reviews, Dec. 1986, pp. 381-400.
5. Barbour et al. "Heterogeneity of Major Proteins in Lyme Disease *Borreliae*: A Molecular Analysis of North American and European Isolates," Journal of Infectious Diseases, September 1985, Vol. 152, No. 3., pp. 478-484.
6. Barbour et al. "Lyme Disease Spirochetes and Ixodid Tick Spirochetes Share a Common Surface Antigenic Determinant Defined by a Monoclonal Antibody," Infection and Immunity, Aug. 1983, p. 795-804
7. Barbour et al. "Variation in a Major Surface Protein of Lyme Disease Spirochetes," Infection and Immunity, July 1984, pp. 94-100.
8. Barstad et al. "Variable Major Proteins of *Borrelia Hermsii*," Journal of Experimental Medicine, June 1985, Vol. 161, pp. 1302-1314.
9. Brandt et al. "Immunogenic Integral Membrane Proteins of *Borrelia Burgdorferi* Are Lipoproteins." Infection and Immunity, April 1990, Vol. 58, No. 4, pp. 983-991.
10. Bencah, et al. "A Murine IgM Monoclonal Antibody Binds an Antigenic Determinant in Outer Surface Protein A, An Immunodominant Basic Protein of the Lyme Disease Spirochete" The Journal of Immunology, January 1, 1988, Vol. 140, 265-272, No. 1
11. Craft, et al. "Antibody Response in Lyme Disease: Evaluation of Diagnostic Tests" The Journal of Infectious Diseases, May 1984, Vol. 149, No. 5
12. Craft, et. al. "Antigens of *Borrelia burgdorferi* Recognized during Lyme Disease"
13. Fikrig, et al. "Long-Term Protection of Mice from Lyme Disease by Vaccination with OspA" Infection and Immunity, March 1992, p. 773-777
14. Yigong Ge and Nyles W. Charon "FlaA, A Putative Flagellar Outer Sheath Protein, Is Not an Immunodominant Antigen Associated with Lyme Disease" Infection and Immunity, July 1997, p. 2992-2995
15. Yigong Ge and Nyles W. Charon "An Unexpected flaA Homolog Is Present and Expressed in *Borrelia burgdorferi*" Journal of Bacteriology, January 1997, p. 552-556
16. Robert L. Gordzicki and Allen C. Steere "Comparison of Immunoblotting and Indirect Enzyme-Linked Immunosorbent Assay Using Different Antigen Preparations for Diagnosing Early Lyme Disease" The Journal of Infectious Diseases, April 1988, Vol. 157, No. 4
17. Hansen, et al. "Immunochemical Characterization of and Isolation of the Gene for a *Borrelia burgdorferi* Immunodominant 60-Kilodalton Antigen Common to a Wide Range of Bacteria" Infection and Immunity, August 1988, p. 2047-2053
18. Hansen, et al. "Measurement of Antibodies to the *Borrelia burgdorferi* Flagellum Improves Serodiagnosis in Lyme Disease" Journal of Clinical Microbiology, February 1988, p. 338-346
19. Howe, et al. "Organization of Genes Encoding Two Outer Membrane Proteins of the Lyme Disease Agent *Borrelia burgdorferi* within a Single Transcriptional Unit" Infection and Immunity, October 1986, p. 207-212
20. Howe, et al. "A Single Recombinant Plasmid Expressing Two major Outer Surface Proteins of the Lyme Disease Spirochete" Science Volume 227, 1 October 1984; accepted 30 October 1984
21. Frederick W. Hyde and Russell C. Johnson "Genetic Relationship of Lyme Disease Spirochetes to *Borrelia*, *Treponema*, and *Leptospira* spp" Journal of Clinical Microbiology, August 1984, p. 151
22. Magnarelli, et al. "Comparison of an Indirect Fluorescent Antibody Test with an Enzyme-Linked Antigen" Infection and Immunity, October 1992, p. 4309-4311
23. Magnarelli, et al. "Comparison of an Indirect Fluorescent Antibody Test with an Enzyme-Linked Antigen" Infection and Immunity, October 1992, p. 4309-4311
24. Magnarelli, et al. "Comparison of an Indirect Fluorescent Antibody Test with an Enzyme-Linked

Immunosorbent Assay for Serological Studies of Lyme Disease" Journal of Clinical Microbiology, August 1984, p. 181-184

25. Magnarelli, et al. "Cross-Reactivity in Serological Tests for Lyme Disease and Other Spirochetal Infections" The Journal of Infectious Diseases July 1987, Vol. 156, No. 1

26. Neil Margolis and Patricia A. Rosa "Regulation of Expression of Major Outer Surface Proteins in *Borrelia burgdorferi*" Infection and Immunity May 1993, p. 2207-2210

27. Sands, et al. "Analysis of North American and European Isolates of *Borrelia burgdorferi* with Antiserum to a Recombinant Antigen" The Journal of Infectious Diseases August 1989, Vol. 160, No. 2

28. Padula, et al. "Use of Recombinant OspC from *Borrelia burgdorferi* for Serodiagnosis of Early Lyme Disease" J. Clin. Microbiol. 1994, Vol. 32

29. Rasiah, et al. "Use of a Hybrid Protein Consisting of the Variable Region of the *Borrelia burgdorferi* Flagellin and Part of the 83-kDa Protein as Antigen for Serodiagnosis of Lyme Disease" J. Clin. Microbiol. April 1994, p. 1011-1017

30. Sadziene, et al. "Borrelia burgdorferi Mutant Lacking Osp: Biological and Immunological Characterization" Infection and Immunity, April 1995, p. 1573-1580

31. Schaible, et al. "Monoclonal antibodies specific for the outer surface protein A (OspA) of *Borrelia burgdorferi* prevent Lyme borreliosis in severe combined immunodeficiency (scid) mice" Proc. Natl. Acad. Sci USA May 1990, Vol. 87, pp. 3768-3772

32. Schneider, et al. "Prognostic B-Cell Epitopes on the Flagellar Protein of *Borrelia burgdorferi*" Infection and Immunity January 1992, p. 316-319

33. Simpson, et al. "Antibody to a 39-Kilodalton *Borrelia burgdorferi* Antigen (P39) as a Marker for Infection in Experimentally and naturally Inoculated Animals" Journal of Clinical Microbiology, February 1991, p. 236-243

34. Simpson, et al. "Reactivity of Human Lyme Borreliosis Sera with a 39-Kilodalton Antigen Specific to *Borrelia burgdorferi*" Journal of Clinical Microbiology June 1990, p. 1329-1337

35. Steere, et al. "The Early Clinical Manifestations of Lyme Disease" Annals of Internal Medicine July 1983 Vol. 99, No. 7

36. Steere, et al. "Chronic Lyme Arthritis" Annals of Internal Medicine June 1979, Vol. 90, No. 6

37. Steere, et al. "The Spirochetal Etiology of Lyme Disease" New England Journal of Medicine March 31, 1983, Vol. 308, No. 13

38. Steere, et al. "Lyme Carditis: Abnormalities of Lyme Disease" Annals of Internal Medicine July 1980, Vol. 93, No. 1

39. Steere, et al. "Lyme Carditis: Cardiac Abnormalities of Lyme Disease" Annals of Internal Medicine July 1980, Vol. 93, No. 1

40. Wilske, et al. "Intrathecal Production of Specific Antibodies against *Borrelia burgdorferi* in Patients with Lymphocytic Meningoradiculitis (Bannwarth's Syndrome)" The Journal of Infectious Diseases, February 1986, Vol. 153, No. 2

41. Zhang, et al. "Borrelia burgdorferi Enzyme-linked Immunosorbent Assay for Discrimination of OspA Vaccination from Spirochete Infection" Journal of Clinical Microbiology January 1997, Vol. 35 No. 1

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the

use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

The present Disclosure Statement is being submitted in compliance with 37 CFR 1.56 insofar as an Examiner might consider any of the cited documents important in deciding whether to allow the application to issue as a patent, but the citation of each document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and 1.106(b) and, in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Date: 4/13/95


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